



1647

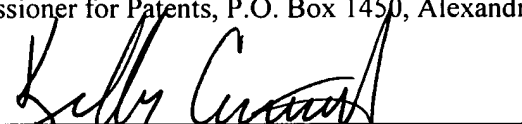
PATENT  
Attorney Docket No. MRK-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Way  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: Erythropoietin Forms with Improved Properties

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 1<sup>st</sup> day of April, 2005.

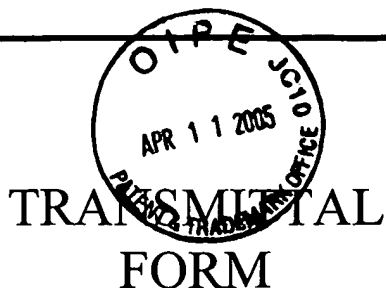
  
Kelly B. Carmataro

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 pg.);
2. Supplemental Information Disclosure Statement (2 pgs.);
3. PTO Form 1449 (11 pgs.) (including cited references B108-B118 and C265-C419); and
4. Return Receipt Postcard.



Application Serial Number	09/708,506
Filing Date	November 9, 2000
First Named Inventor	Way
Group Art Unit	1647
Examiner Name	DeBerry, Regina M.
Attorney Docket No.	MRK-001
Patent No.	Not applicable
Issue Date	Not applicable

**ENCLOSURES (check all that apply)**

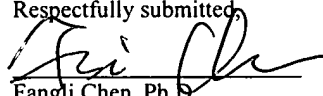
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form  <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets <u>  </u> ]  <input type="checkbox"/> Petition for Extension of Time  <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations (B108-B118 and C265-C419) <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application  <input type="checkbox"/> Formal Drawing(s)  <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal  <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application <input type="checkbox"/> Small Entity Statement  <input type="checkbox"/> CD(s) for large table or computer program  <input type="checkbox"/> Amendment After Allowance  <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences  <input type="checkbox"/> Appeal Brief (in triplicate)  <input type="checkbox"/> Status Inquiry <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8  <input type="checkbox"/> Additional Enclosure(s) (please identify below)
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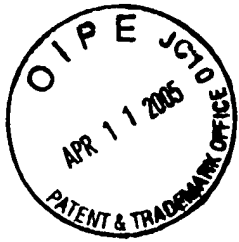
**CORRESPONDENCE ADDRESS**

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**SIGNATURE BLOCK**

Date: April 1, 2005  
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 Tel. No.: (617) 261-3198  
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Respectfully submitted,  
  
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PATENT  
Attorney Docket No. MRK-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SERIAL NO.: 09/708,506 GROUP NO.: 1647  
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Commissioner for Patents  
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Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the non-U.S. patent documents and non-patent publications are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) above but before the mailing date of any of a **final action** under 37 C.F.R. 1.113, a **notice of allowance** under 37 C.F.R. 1.311, or an action that otherwise closes prosecution in the application, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein; or

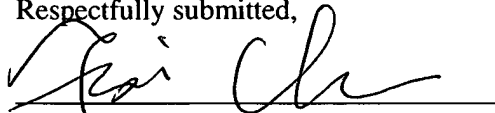
- ☐ (3) after the period defined in (2) above but before the payment of the issue fee, AND
- ☐ the requisite Statement is below, AND
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Date: April 1, 2005  
Reg. No. 51,551

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Fax No.: (617) 261-3175

Respectfully submitted,



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FORM PTO - 1449

SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT

ATTORNEY DOCKET NO.: MRK-001

APPLICANT(S): Way

SERIAL NO.: 09/708,506

CONF. NO.: 2626

FILING DATE: November 9, 2000

GROUP: 1647

## U.S. PATENT DOCUMENTS

AM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A114	4,522,811	6/1/85	Eppstein <i>et al.</i>			
	A115	4,667,016	5/19/87	Lai <i>et al.</i>			
	A116	4,732,683	3/22/88	Georgiades <i>et al.</i>			
	A117	4,737,462	4/12/88	Mark <i>et al.</i>			
	A118	4,975,369	12/4/90	Beavers <i>et al.</i>			
	A119	5,082,658	1/21/92	Palladino			
	A120	5,091,513	2/25/92	Huston <i>et al.</i>			
	A121	5,399,346	3/21/95	Anderson <i>et al.</i>			
	A122	5,428,130	6/27/95	Capon <i>et al.</i>			
	A123	5,480,981	1/2/96	Goodwin <i>et al.</i>			
	A124	5,589,466	12/31/96	Felgner <i>et al.</i>			
	A125	5,614,184	3/25/97	Sytkowski <i>et al.</i>			
	A126	5,712,120	1/27/98	Rodriguez <i>et al.</i>			
	A127	5,738,852	4/14/98	Robinson <i>et al.</i>			
	A128	5,795,779	8/18/98	McCormick			
	A129	5,827,703	10/27/98	Debs <i>et al.</i>			
	A130	5,837,821	11/17/98	Wu <i>et al.</i>			
	A131	6,281,010	8/28/01	Gao <i>et al.</i>			
	A132	6,291,158	9/18/01	Winter <i>et al.</i>			
	A133	6,627,615	9/30/03	Debs <i>et al.</i>			

EXAMINER

DATE CONSIDERED

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ATTORNEY DOCKET NO.: MRK-001

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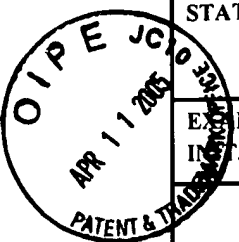
GROUP: 1647

## FOREIGN PATENT DOCUMENTS

EXAM UNIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B108	0 428 267 B1	12/11/96	EP					Y
	B109	0 428 596 B1	4/17/96	EP					Y
	B110	0 433 827 B1	3/4/98	EP					Y
	B111	0 519 596 A1	12/23/92	EP					Y
	B112	0 668 351 B1	9/22/99	EP					Y
	B113	0 699 755 A2	3/6/96	EP					Y
	B114	2 188 638	10/7/87	GB					Y
	B115	WO 92/10755	6/25/92	PCT					Y
	B116	WO 94/25609	11/10/94	PCT					Y
	B117	WO 96/40792	12/19/96	PCT					Y
	B118	WO 00/01822	1/13/00	PCT					Y

EXAMINER

DATE CONSIDERED



FORM PTO - 1449		ATTORNEY DOCKET NO.: MRK-001	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Way	
		SERIAL NO.: 09/708,506	CONF. NO.: 2626
		FILING DATE: November 9, 2000	GROUP: 1647
EXAM. INVENT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C265	Aichele <i>et al.</i> , (1994), "Peptide-Induced T-Cell Tolerance to Prevent Autoimmune Diabetes in a Transgenic Mouse Model," <u>Proc. Natl. Acad. Sci. USA</u> , 91:444-448.	
	C266	Altschul <i>et al.</i> , (1990), "Basic Local Alignment Search Tool," <u>J. Mol. Biol.</u> , 215:403-10.	
	C267	Altschul <i>et al.</i> , (1997), "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search Programs," <u>Nucleic Acids Res.</u> , 25(17):3389-3402.	
	C268	Anderson <i>et al.</i> , (1980), "Characterization of the Fc Receptor for IgG on a Human Macrophage Cell Line U937," <u>J. Immunol.</u> , 125(6):2735-41.	
	C269	Anderson <i>et al.</i> , (1994), "Effects of Route and Formulation on Clinical Pharmacokinetics of Interleukin-2," <u>Clin. Pharmacokinet.</u> , 27(1):19-31.	
	C270	Baici <i>et al.</i> , (1980), "Kinetics of the Different Susceptibilities of the Four Human Immunoglobulin G Subclasses to Proteolysis by Human Lysosomal Elastase," <u>Scand. J. Immunol.</u> , 12(1):41-50.	
	C271	Barbulescu <i>et al.</i> , (1998), "IL-12 and IL-18 Differentially Regulate the Transcriptional Activity of the Human IFN- $\gamma$ Promoter in Primary CD4+ T Lymphocytes," <u>J. Immunol.</u> , 160:3642-7.	
	C272	Bednarek <i>et al.</i> , (1991), "Soluble HLA-A2.1 Restricted Peptides that are Recognized by Influenza Virus Specific Cytotoxic T Lymphocytes," <u>J. Immunol. Methods</u> , 139:41-47.	
	C273	Benacerraf <i>et al.</i> , (1959), "The Clearance of Antigen Antibody Complexes from the Blood by the Reticulo-Endothelial System," <u>J. Immunol.</u> , 82:131-7.	
	C274	Böhm, (1994), "On the Use of LUDI to Search the Fine Chemicals Directory for Ligands of Proteins of Known Three-Dimensional Structure," <u>J. Comput. Aided Mol. Des.</u> , 8:623-32.	
	C275	Böhm, (1994), "The Development of a Simple Empirical Scoring Function to Estimate the Binding Constant for a Protein-Ligand Complex of Known Three-Dimensional Structure," <u>J. Comput. Aided Mol. Des.</u> , 8(3):243-56.	
	C276	Böhm, (1998), "Prediction of Binding Constants of Protein Ligands: A Fast Method for the Prioritization of Hits Obtained from De Novo Design or 3D Database Search Programs," <u>J. Comput. Aided Mol. Des.</u> , 12(4):309-23.	
	C277	Boshart <i>et al.</i> , (1985), "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <u>Cell</u> , 41:521-530.	
	C278	Boulianne <i>et al.</i> , (1984), "Production of Functional Chimaeric Mouse/Human Antibody," <u>Nature</u> , 312:643-6.	
	C279	Bourgeois <i>et al.</i> , (1974), "Determination of the Primary Structure of a Mouse IgG2a Immunoglobulin Amino Acid Sequence of the Fc Fragment: Implications for the Evolution of Immunoglobulin Structure and Function," <u>Eur. J. Biochem.</u> , 43:423-35.	
	C280	Brambell <i>et al.</i> , (1964), "A Theoretical Model of $\gamma$ -Globulin Catabolism," <u>Nature</u> , 203:1352-55.	
	C281	Brazolot Millan <i>et al.</i> , (1998), "Cpg DNA Can Induce Strong TH1 Humoral and Cell-Mediated Immune Responses against Hepatitis B Surface Antigen in Young Mice," <u>Proc. Natl. Acad. Sci. USA</u> , 95:15553-8.	
	C282	Brekke <i>et al.</i> , (1994), "Human IgG Isotype-Specific Amino Acid Residues Affecting Complement-Mediated Cell Lysis and Phagocytosis," <u>Eur. J. Immunol.</u> , 24:2542-2547.	
EXAMINER		DATE CONSIDERED	

FORM PTO - 1449

SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT

ATTORNEY DOCKET NO.: MRK-001

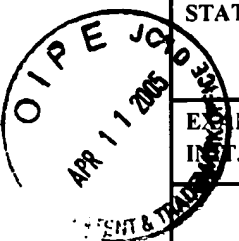
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EXAM. INST.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C283 Brem <i>et al.</i> , (1993), "The Combination of Antiangiogenic Agents to Inhibit Primary Tumor Growth and Metastasis," <u>J. Pediatr. Surg.</u> , 28(10):1253-7.
	C284 Brooks <i>et al.</i> , (1983), "CHARMM: A Program for Macromolecular Energy Minimization and Dynamics Calculations," <u>J. Comput. Chemistry</u> , 4:187-217.
	C285 Broudy <i>et al.</i> , (1988), "Recombinant Human Erythropoietin: Purification and Analysis of Carbohydrate Linkage," <u>Arch. Biochem. Biophys.</u> , 265:329-36.
	C286 Bubenik <i>et al.</i> , (1995), "Interleukin-2 Gene Therapy of Residual EL-4 Leukaemia Potentiates the Effect of Cyclophosphamide Pretreatment," <u>J. Cancer Res. Clin. Oncol.</u> , 121:39-43.
	C287 Bumol <i>et al.</i> , (1982), "Unique Glycoprotein-Proteoglycan Complex Defined by Monoclonal Antibody on Human Melanoma Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 79:1245-9.
	C288 Carnemolla <i>et al.</i> , (1989), "A Tumor-Associated Fibronectin Isoform Generated by Alternative Splicing of Messenger RNA Precursors," <u>J. Cell. Biol.</u> , 108:1139-1148.
	C289 Carnemolla <i>et al.</i> , (1992), "The Inclusion of the Type III Repeat ED-B in the Fibronectin Molecule Generates Conformational Modifications that Unmask a Cryptic Sequence," <u>J. Biol. Chem.</u> , 267(34):24689-24692.
	C290 Cazzola <i>et al.</i> , (1998), "Red Blood Cell Precursor Mass as an Independent Determinant of Serum Erythropoietin Level," <u>Blood</u> , 91:2139-45.
	C291 Chan <i>et al.</i> , (1992), "Mechanisms of IFN- $\gamma$ Induction by Natural Killer Cell Stimulatory Factor (NKSF/IL-12). Role of Transcription and mRNA Stability in the Synergistic Interaction Between NKSF and IL-2," <u>J. Immunol.</u> , 148:92-98.
	C292 Chappel <i>et al.</i> , (1991), "Identification of the Fc Gamma Receptor Class I Binding Site In Human IgG Through Use of Recombinant IgG1/IgG2 Hybrid and Point-Mutated Antibodies," <u>Proc. Natl. Acad. Sci. USA</u> , 88(20):9036-40.
	C293 Cheetham, (1998), "NMR Structure of Human Erythropoietin and a Comparison with its Receptor Bound Conformation," <u>Nat. Struct. Biol.</u> , 5:861-6.
	C294 Ciardiello <i>et al.</i> , (1996), "Antitumor Activity of Combined Blockade of Epidermal Growth Factor Receptor and Protein Kinase A," <u>J. Natl. Cancer Inst.</u> , 88:1770-6.
	C295 Cirulli <i>et al.</i> , (1998), "KSA Antigen Ep-CAM Mediates Cell-Cell Adhesion of Pancreatic Epithelial Cells: Morphoregulatory Roles in Pancreatic Islet Development," <u>J. Cell Biol.</u> , 140:1519-34.
	C296 Cohen <i>et al.</i> , (1998), "An Artificial Cell-Cycle Inhibitor Isolated from a Combinatorial Library," <u>Proc. Natl. Acad. Sci. USA</u> , 95:14272-7.
	C297 Congote <i>et al.</i> , (1984), The Erthrotropins, New Erythroid Cell Stimulate Factors Extracted From Human and Bovine Fetal Tissues," Abstract 364, "Proceedings 7 <sup>th</sup> Intl. Congress of Endocrinology," Quebec City, Quebec, July 1-7, 1984.
	C298 Congote, (1983), "Isolation of Two Biologically Active Peptides, Erythrotropin I and Erythrotropin II from Fetal Calf Intestine," <u>Biochem. Biophys. Res. Commun.</u> , 115(2):477-83.
	C299 Congote, (1984), "Extraction from Fetal Bovine Serum of Erythrotropin, an Erythroid Cell-Stimulating Factor," <u>Anal. Biochem.</u> , 140:428-33.

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DATE CONSIDERED



FORM PTO - 1449

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EXAM.  
M.  
PATENT & TRADEMARK

## OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

C300	Connor <i>et al.</i> , (2004), "Ex vivo Evaluation of Anti-EpCAM Immunocytokine huKS-IL2 in Ovarian Cancer," <u>J. Immunotherapy</u> , 27:211-219.
C301	Cosenza <i>et al.</i> , (1997), "Disulfide Bond Assignment in Human Interleukin-7 by Matrix-Assisted Laser Desorption/Ionization Mass Spectroscopy and Site-Directed Cysteine to Serine Mutational Analysis," <u>J. Biol. Chem.</u> , 272:32995-3000.
C302	Cunningham <i>et al.</i> , (1989), "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis," <u>Science</u> , 244:1081-85.
C303	Curiel <i>et al.</i> , (1991), "Adenovirus Enhancement of Transferrin-Polylysine-Mediated Gene Delivery," <u>Proc. Natl. Acad. Sci. USA</u> , 88:8850-4.
C304	Dauber-Osguthorpe <i>et al.</i> , (1988), "Structure and Energetics of Ligand Binding to Proteins: Escherichia Coli Dihydrofolate Reductase-Trimethoprim, A Drug-Receptor System," <u>Proteins</u> , 4:31-47.
C305	Daugherty <i>et al.</i> , (1991), "Polymerase Chain Reaction Facilitates the Cloning, CDR-Grafting, and Rapid Expression of a Murine Monoclonal Antibody Directed Against the CD18 Component of Leukocyte Integrins," <u>Nucleic Acid Res.</u> , 19:2471-2476.
C306	De Bruijn <i>et al.</i> , (1995), "Phagocyte-Induced Antigen-Specific Activation of Unprimed CD8+ T Cells in Vitro," <u>Eur. J. Immunol.</u> , 25:1274-85.
C307	Delorme <i>et al.</i> , (1992), "Role of Glycosylation on the Secretion and Biological Activity of Erythropoietin," <u>Biochemistry</u> , 31:9871-6.
C308	Desai <i>et al.</i> , (1992), "IL-12 Receptor. II. Distribution and Regulation of Receptor Expression," <u>J. Immunol.</u> , 148:3125-32.
C309	Donnelly <i>et al.</i> , (1993), "Targeted Delivery of Peptide Epitopes to Class I Major Histocompatibility Molecules by a Modified Pseudomonas Exotoxin," <u>Proc. Natl. Acad. Sci. USA</u> , 90:3530-4.
C310	Donnelly <i>et al.</i> , (1997), "DNA Vaccines," <u>Annu. Rev. Immunol.</u> , 15:617-48.
C311	Dube <i>et al.</i> , (1988), "Glycosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," <u>J. Biol. Chem.</u> , 263:17516-21.
C312	Ellison <i>et al.</i> , (1982), "The Nucleotide Sequence of a Human Immunoglobulin C $\gamma_1$ Gene," <u>Nucleic Acids Res.</u> , 10:4071-9.
C313	Faas <i>et al.</i> , (1993), "Phenotypically Diverse Mouse Thymic Stromal Cell Lines which Induce Proliferation and Differentiation Of Hematopoietic Cells," <u>Eur. J. Immunol.</u> , 23:1201-14.
C314	Farner <i>et al.</i> , (1995), "Distinction Between $\gamma_c$ C Detection and Function in YT Lymphoid Cells and in the Granulocyte-Macrophage Colony-Stimulating Factor-Responsive Human Myeloid Cell Line, Tf-1," <u>Blood</u> , 86:4568-78.
C315	Fawell <i>et al.</i> , (1994), "Tat-Mediated Delivery of Heterologous Proteins into Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 91:664-8.
C316	Fu <i>et al.</i> , (1993), "The Sheep Erythropoietin Gene: Molecular Cloning and Effect of Hemorrhage on Plasma Erythropoietin and Renal/Liver Messenger RNA in Adult Sheep," <u>Mol. Cell. Endocrinol.</u> , 93:107-16.
C317	Gainsford <i>et al.</i> , (1996), "Leptin Can Induce Proliferation, Differentiation, and Functional Activation of Hemopoietic Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 93:14564-14568.

EXAMINER

DATE CONSIDERED

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EX-101  
JAN 11 2006  
PATENT & TRADEMARK OFFICE

## OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

C318	Gammon <i>et al.</i> , (1992), "Endogenous Loading of HLA-A2 Molecules with an Analog of the Influenza Virus Matrix Protein-Derived Peptide and Its Inhibition By An Exogenous Peptide Antagonist," <u>J. Immunol.</u> , 148:7-12.
C319	Ghetie <i>et al.</i> , (1990), "Disseminated or Localized Growth of a Human B-Cell Tumor (Daudi) in SCID Mice," <u>Intl. J. Cancer</u> , 45:485.
C320	Ghetie <i>et al.</i> , (1997), "FcRn: The MHC Class I-Related Receptor that is More Than an IgG Transporter," <u>Immunology Today</u> , 18(12):592-598.
C321	Goldwasser <i>et al.</i> , (1971), "Purification of Erythropoietin," <u>Proc. Natl. Acad. Sci. USA</u> , 68:697-8.
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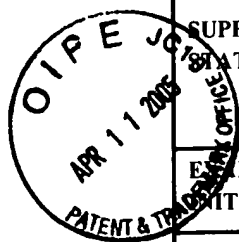
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